

WHAT IS CLAIMED IS:

1. A method for stabilization of a physiologically active peptide in a process of preparing a powder containing the physiologically active peptide by drying an aqueous liquid containing the physiologically active peptide, wherein the method comprises adding to the aqueous liquid at least one compound selected from the group consisting of a nonionic surfactant, a water-soluble, nonionic, organic binder, hydrogenated lecithin, and mannitol.
2. A method for stabilization of a physiologically active peptide in a process of preparing a powder containing the physiologically active peptide by drying an aqueous liquid containing the physiologically active peptide, wherein the method comprises adding to the aqueous liquid mannitol and at least one compound selected from the group consisting of a nonionic surfactant, a water-soluble, nonionic, organic binder, and hydrogenated lecithin.
3. A method for stabilization of a physiologically active peptide in a process of preparing a powder containing the physiologically active peptide by drying an aqueous liquid containing the physiologically active peptide, wherein the method comprises adding to the aqueous liquid at least one component selected from the group consisting of a nonionic surfactant in an amount of 0.01-0.5 % by weight, a water-soluble, nonionic, organic binder in an amount of 0.01-1 % by weight, hydrogenated lecithin, and 1-50 parts by weight of mannitol per one part by weight of the physiologically active peptide.
4. A method for stabilization of a physiologically active peptide in a process of preparing a powder containing the physiologically active peptide by drying an aqueous liquid containing the physiologically active peptide, wherein the method comprises adding to the aqueous liquid 1-50 parts by weight of mannitol per one part by weight of the physiologically active peptide and at least one component selected from the group consisting of a nonionic surfactant in an amount of 0.01-0.5 % by weight, a water-soluble, nonionic, organic binder in an amount of 0.01-1 % by weight, and hydrogenated lecithin.
5. The method of one of claims 1 to 4 wherein the water-soluble, nonionic, organic binder is selected from the group consisting of polyvinylpyrrolidone, a water-soluble, nonionic cellulose derivative, and polyvinylalcohol.
6. The method of claim 5 wherein the water-soluble, nonionic cellulose

derivative is selected from the group consisting of hydroxypropylcellulose, hydroxyethylcellulose, and hydroxypropylmethylcellulose.

Sub A2 7. The method of one of claims 1 to 6 wherein the nonionic surfactant is selected from the group consisting of polysorbate, polyoxyethylenehydrogenated castor oil, and a poloxamer.

8. The method of one of claims 1 to 7 wherein drying of the aqueous liquid is performed by spray drying, lyophilization or spray-freeze drying, or by coating which may be fluid-bed coating, or performed in fluid-bed granulation.

9. The method of one of claims 1 to 8 wherein the average size of the particles making up the powder is 1-10 μ m.

10. The method of one of claims 1 to 9 wherein the physiologically active peptide is selected from the group consisting of growth hormones, insulins, calcitonins, erythropoietin, glucagon, somatostatin, somatostatin derivatives, interferons, interleukins, superoxide dismutase, urokinase, proteases, tumor necrosis factors, colony-stimulating factors, kallikrein, lysozyme, fibronectin, insulin-like growth factors, epidermal growth factor, fibroblast growth factors, platelet-derived growth factor, nerve growth factor, hepatocyte growth factor, vasculogenesis factors, and anti-vasculogenesis factors.

11. The method of one of claims 1 to 9 wherein the physiologically active peptide is human growth hormone or human insulin.

12. The method of one of claims 1 to 9 wherein the physiologically active peptide is human growth hormone.

13. A method for preparation of a powder containing a physiologically active peptide, wherein the method comprises forming a powder by drying an aqueous liquid containing a physiologically active peptide and at least one compound selected from the group consisting of a nonionic surfactant, a water-soluble, nonionic, organic binder, hydrogenated lecithin, and mannitol.

14. A method for preparation of a powder containing a physiologically active peptide, wherein the method comprises forming a powder by drying an aqueous liquid containing the physiologically active peptide, mannitol, and at least one compound selected from the group consisting of a nonionic surfactant, a water-soluble, nonionic, organic binder, and hydrogenated lecithin.

15. A method for preparation of a powder containing a physiologically active peptide, wherein the method comprises forming a powder by drying an

aqueous liquid containing the physiologically active peptide and at least one component selected from the group consisting of a nonionic surfactant in an amount of 0.01-0.5 % by weight, a water-soluble, nonionic, organic binder in an amount of 0.01-1 % by weight, hydrogenated lecithin and 1-50 parts by weight of mannitol per one part by weight of the physiologically active peptide.

16. A method for preparation of a powder containing a physiologically active peptide, wherein the method comprises forming a powder by drying an aqueous liquid containing the physiologically active peptide, 1-50 parts by weight of mannitol per one part by weight of the physiologically active peptide, and at least one component selected from the group consisting of a nonionic surfactant in an amount of 0.01-0.5 % by weight, a water-soluble, nonionic, organic binder in an amount of 0.01-1 % by weight, and hydrogenated lecithin.

Sub B 17. The method for preparation of a powder containing a physiologically active peptide of one of claims 13 to 16, wherein the water-soluble, nonionic, organic binder is selected from the group consisting of polyvinylpyrrolidone, a water-soluble, nonionic cellulose derivative, and polyvinylalcohol.

18. The method for preparation of a powder containing a physiologically active peptide of claim 17, wherein the water-soluble, nonionic cellulose derivative is selected from the group consisting of hydroxypropylcellulose, hydroxyethylcellulose, and hydroxypropylmethylcellulose.

Sub A 19. The method for preparation of a powder containing a physiologically active peptide of one of claims 13 to 18, wherein the nonionic surfactant is selected from the group consisting of polysorbate, polyoxyethylenedihydrogenated castor oil, and a poloxamer.

20. The method for preparation of a powder containing a physiologically active peptide of one of claims 13 to 19, wherein drying of the aqueous liquid is performed by spray drying, lyophilization or spray-freeze drying, or by coating which may be fluid-bed coating, or performed in fluid-bed granulation.

21. The method for preparation of a powder containing a physiologically active peptide of one of claims 13 to 20 wherein the average size of the particles making up the powder is 1-10 μ m.

22. The method for preparation of a powder containing a physiologically active peptide of one of claims 13 to 21, wherein the physiologically active peptide is selected from the group consisting of growth hormones, insulins, calcitonins,

Sub A4

erythropoietin, glucagon, somatostatin, somatostatin derivatives, interferons, interleukins, superoxide dismutase, urokinase, proteases, tumor necrosis factors, colony-stimulating factors, kallikrein, lysozyme, fibronectin, insulin-like growth factors, epidermal growth factor, fibroblast growth factors, platelet-derived growth factor, nerve growth factor, hepatocyte growth factor, vasculogenesis factors, and anti-vasculogenesis factors.

23. The method for preparation of a powder containing a physiologically active peptide of one of claims 13 to 21, wherein the physiologically active peptide is human growth hormone or human insulin.

24. The method for preparation of a powder containing a physiologically active peptide of one of claims 13 to 21, wherein the physiologically active peptide is human growth hormone.

25. A powder containing a physiologically active peptide, wherein the powder is made up of particles comprising a physiologically active peptide and mannitol at a weight proportion of 1:1 to 1:50.

26. The powder containing a physiologically active peptide of claim 25, wherein the particles further comprise per one part by weight of the physiologically active peptide at least one component selected from the group consisting of a nonionic surfactant in an amount of 0.05-3 parts by weight, a water-soluble, nonionic, organic binder in an amount of 0.05-6 parts by weight, and hydrogenated lecithin.

Sub A5 27. The powder containing a physiologically active peptide of claim 25 or 26, wherein the average size of the particles is 1-10 μ m.

28. The powder containing a physiologically active peptide of one of claims 25 to 27, for which drying of the aqueous solution was performed by spray drying, spray-freeze drying, or lyophilization.

29. The powder containing a physiologically active peptide of one of claims 25 to 28, wherein the physiologically active peptide is selected from the group consisting of growth hormones, insulins, calcitonins, erythropoietin, glucagon, somatostatin, somatostatin derivatives, interferons, interleukins, superoxide dismutase, urokinase, proteases, tumor necrosis factors, colony-stimulating factors, kallikrein, lysozyme, fibronectin, insulin-like growth factors, epidermal growth factor, fibroblast growth factors, platelet-derived growth factor, nerve growth factor, hepatocyte growth factor, vasculogenesis factors, and anti-vasculogenesis factors.

Sub AS

30. The powder containing a physiologically active peptide of one of claims 25 to 28, wherein the physiologically active peptide is human growth hormone or human insulin.

31. The powder containing a physiologically active peptide of one of claims 25 to 28, wherein the physiologically active peptide is human growth hormone.

32. An inhalant composition containing a physiologically active peptide, wherein the inhalant composition comprises particles as defined in one of claims 25 to 31.

add
B1

RECEIVED SEP 11 2000